

REMARKS

The Office Action dated July 28, 2004, has been received and reviewed. Claims 32 and 34-35 are pending in the present application. Claims 32 and 34-35 stand rejected. Applicants respectfully request reconsideration of the application in view of the arguments below.

I. Rejections under 35 U.S.C. §§ 102(b) and (e)

A. Claim 32

Claim 32 stands rejected under 35 U.S.C. §§ 102(b) and 102(e) as being anticipated by Kaken Pharm Co. Ltd. (JP 10279483) (hereinafter "Kaken"). Applicants respectfully traverse this rejection for the reasons discussed below.

Case law holds and the M.P.E.P. states that a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Furthermore, the identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Additionally, anticipation under 35 U.S.C. § 102 requires the disclosure in a single piece of prior art of **each and every limitation** of a claimed invention. *Apple Computer Inc. v. Articulate Systems Inc.* 57 USPQ2d 1057, 1061 (Fed. Cir. 2000).

Applicants submit that Kaken does not anticipate Claim 32 of the present application. Applicants submit that Kaken discloses an estrogen and androgen combination wherein the estrogen compounds include estrone and 17 β -estradiol. However, Kaken does not disclose the specific mixture of estrogenic compounds as recited in Claim 32. Claim 32 recites a mixture of estrogenic compounds, wherein said mixture "comprises salts of conjugated estrone, conjugated equilin, conjugated $\Delta^{8,9}$ -dehydroestrone, conjugated 17 α -estradiol, conjugated 17 β -dihydroequilin, conjugated 17 α -dihydroequilin, conjugated 17 β -estradiol, conjugated equilinenin, conjugated 17 α -dihydroequilenin, and conjugated 17 β -dihydroequilenin". The presently claimed composition recites a mixture of different conjugated estrogens as compared to the Kaken reference. Thus, Kaken fails to disclose the specific

conjugated estrogens as set forth in Claim 32. Therefore, Applicants submit Kaken et al. does not anticipate all of the elements recited in Claim 32 of the present application. Accordingly, Applicants respectfully request reconsideration of the rejection of Claim 32 under 35 U.S.C. § 102(b).

B. Claim 34

Claim 34 stands rejected under 35 U.S.C. § 102(e) as being anticipated by Martin et al. (WO 00/74684A1). Applicants respectfully traverse this rejection for the reasons discussed below.

Applicants submit that Martin et al. does not anticipate Claim 34 of the present application. Martin et al. discloses an estrogen, a progestin, an androgen, a selective estrogen receptor modulator, a selective androgen receptor modulator, and/or a selective progestin receptor modulator. More specifically, Martin et al. discloses that examples of suitable estrogens include conjugated estrogens, esterified estrogens, estradiol valerate, estradiol benzoate, 17 β -estradiol, estradiol cypionate, estrone, piperazine estrone sulfate, estriol, ethyl estradiol, polyestradiol phosphate, estrone potassium sulfate, benzestrol, chlorotrianisene, methallenestril, dienestrol, diethylstilbestrol diphosphate, mestranol, diethylstilbestrol (DES), quinestranol, and phytoestrogens. Martin et al. also disclose that animal-derived estrogens (e.g., 25 equine estrogens) and their metabolic derivatives also are suitable for use in the invention. However, Martin et al. fails to disclose a composition of a mixture of estrogenic compounds wherein said mixture "comprises salts of conjugated estrone, conjugated equilin, conjugated $\Delta^{8,9}$ -dehydroestrone, conjugated 17 α -estradiol, conjugated 17 β -dihydroequilin, conjugated 17 α -dihydroequilin, conjugated 17 β -estradiol, conjugated equilenin, conjugated 17 α -dihydroequilenin, and conjugated 17 β -dihydroequilenin". Therefore, Martin et al. fails to disclose each and every limitation of Claim 34 of the present application. Accordingly, Applicants respectfully request reconsideration and withdrawal of the 35 U.S.C. § 102(e) rejection to Claim 34.

C. Claim 35

Claim 35 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Huber et al., U.S. Patent No. 5,908,638. Applicants respectfully traverse this rejection for the reasons discussed below.

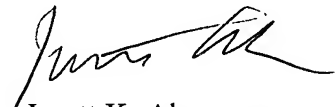
Applicants submit that Huber et al. does not anticipate Claim 35 of the present application. Huber et al. discloses the use of estrogens such as equilin, estrone, 17 α -dihydroequilin, 17 β -dihydroequilin and 17 α -estradiol and their corresponding sulfate esters. Huber et al. also discusses a composition containing a progestogen. However, similar to Martin and Kaken, Huber et al. fails to disclose a composition consisting essentially of a mixture of estrogenic compounds wherein said mixture "comprises salts of conjugated estrone, conjugated equilin, conjugated $\Delta^{8,9}$ -dehydroestrone, conjugated 17 α -estradiol, conjugated 17 β -dihydroequilin, conjugated 17 α -dihydroequilin, conjugated 17 β -estradiol, conjugated equilenin, conjugated 17 α -dihydroequilenin, and conjugated 17 β -dihydroequilenin". Because the estrogenic compounds in Huber et al. do not contain this mixture, Huber et al. fails to anticipate **each and every element** of Claim 35 of the present application. Accordingly, Applicants respectfully request reconsideration and withdrawal of the 35 U.S.C. § 102(b) rejection to Claim 35.

CONCLUSION

In view of the remarks presented herein, Applicants respectfully submit that the claims define patentable subject matter. If, in the opinion of the Examiner, a telephonic conference would expedite the examination of this matter, the Examiner is invited to call the undersigned attorney at (919) 854-1400.

It is not believed that an extension of time and/or additional fee(s)-including fees for net addition of claims-are required, beyond those that may otherwise be provided for in documents accompanying this paper. In the event, however, that an extension of time is necessary to allow consideration of this paper, such an extension is hereby petitioned under 37 C.F.R. §1.136(a). Any additional fees believed to be due in connection with this paper may be charged to our Deposit Account No. 50-0220.

Respectfully Submitted,

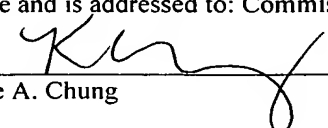

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